REMARKS

Claims 1, 5, 6, 13-15, 19 and 21 are pending in this application. Claims 2-4, 7-12, 16-18, and 20 previously have been canceled. Claim 15 has been amended to recite that the therapeutically effective amount of a botulinum toxin type A is less than an amount that would be used to paralyze a muscle. Support for this amendment may be found, for example, on page 7, ¶ [0069].

No new matter is added by way of this amendment. The Applicant reserves the right to pursue any excised or unclaimed subject matter in continuing applications.

35 U.S.C. §112 Rejections

Claim 13 has been rejected under 35 USC 112, first paragraph, as failing to comply with the written description requirement. Specifically, the Office states that Example 4 only provides support for deriding of pressure sores coupled with topical administration of botulinum toxin. The Applicants respectfully traverse.

The claims need not have *in haec verba* support in the specification. The proper inquiry is whether a skilled artisan would be able to practice the claimed invention without undue experimentation. A skilled artisan in view of the specification and claims would readily envision that any local form of botulinum toxin administration is possible. The specification is replete with language expounding the interchangeability of the various forms of local administration. For example, the specification states that "[m]ethods to apply the *botulinum* toxin includes but not limited to subcutaneous, intradermal, intramuscular, topical, and via slow or extended release implants."[1] Further, "[l]ocal administration of a Clostridial toxin, such as a *botulinum* toxin, can provide a high, local therapeutic level of the toxin."[2] Importantly, the specification

[1] Published Specification, ¶ [0090].
[2] Published Specification, ¶ [0105].

provides that the "neurotoxin may be administered by any suitable method as determined by the attending physician."[3]

In view of the specification and Example 4, a skilled artisan (often a highly-skilled attending physician) would realize that pressure sore debridement may be coupled with *botulinum* toxin application topically[4] or by any other local administration methods disclosed in the specification. Accordingly, the Applicant respectfully requests reconsideration and withdrawal of this rejection.

35 U.S.C. §102 Rejections

Claims 1, 5-6, 15, 19, and 21 are rejected under 35 USC 102(e) as anticipated by U.S. Pat. Pub. 2005/0196414 ("Dake"). The Applicant respectfully traverses. Dake does not disclose the present claims. Specifically, the rejected independent claims 1, 6, and 15 all require that the patient not have contractures or spasticity. However, Dake's treatment includes muscle paralysis, treatment of muscle spasms, and prevention or reduction of dystonia or dystonic contractions.[5] Further, all of the present claims require that the amount of botulinum toxin be less than the amount used to paralyze a muscle, which is in direct contradiction to Dake's treatment, which includes muscle paralysis.[6] Indeed, Dake provides that an "effective amount" of botulinum toxin is an amount "sufficient to produce the desired muscular paralysis or other biological or aesthetic effect . . . ."[7]

In addition, the Office Action states that Dake claims 51, 54, 71, 126, and 141 disclose the present claims. Respectfully, the Office misreads the claims. Dake independent claim 51 is directed to topically applying botulinum toxin while claim 54 is directed to achieving "a desired biologic effect." Claim 71 is directed to buttock application. "Wound healing" is not mentioned until claim 126 and is not dependent on

[3] Published Specification, ¶ [0102].
[4] Published Specification, ¶ [0113].
[5] Dake, ¶¶ [0019], [0056].
[6] Dake, ¶¶ [0019], [0056].
[7] Dake, ¶ [0055].

claim 71. A skilled artisan in view of Dake would not perceive topical application of botulinum toxin to the buttocks for wound healing. In addition, the Dake claims do not disclose, *inter alia*, treatments for pressure sores in therapeutic affective amounts of botulinum toxin type A that do not paralyze. Accordingly, the Applicant respectfully requests withdrawal of this rejection.

Claim 1 also is rejected under 35 USC 102(b) as anticipated by *The New England Journal of Medicine*, Vol. 341, No. 2, pp. 65-69 (1999) ("Brisinda"). The Applicant respectfully traverses. Brisinda does not disclose the present claims since it is directed to the treatment of "chronic anal fissure" using "botulinum toxin injected into the internal anal sphincter on each side of the anterior midline or 0.2 percent nitroglycerin ointment . . . ."[8] Present Claim 1 is for treating "a pressure sore unrelated to contractures or spacticity." However, Brisinda is directed to treatment of chronic anal fissures and states that "chronic anal fissure is associated with spasm of the internal anal sphincter . . . ."[9] Since Brisinda does not teach treatment of a "pressure sore unrelated to contractures or spasticity," Brisinda cannot anticipate claim 1. Accordingly, the Applicant respectfully requests withdrawal of this rejection.

35 U.S.C. §103 Rejections

Claims 1, 5-6, 14-15, 19 are rejected under 35 USC 103(a) as being unpatentable over U.S. Pat. Pub. 2003/0021776 ("Rebar") in view of U.S. Pat. Pub. 2002/0187164 ("Borodic") and U.S. Pat. 6,447,787 ("Gassner"). The Applicant respectfully traverses.

Rebar primarily is directed to zinc finger protein's (ZFP) ability to treat ischemia and facilitate wound healing.[10] Rebar tangentially discloses that "[t]oxin molecules also have the ability to transport polypeptides across cell membranes."[11] Despite the fact that that Rebar generically discloses "toxin molecules" as carriers, the Office opines that

[8] Brisinda, p. 65, 1st col.
[9] Brisinda, p. 68, 2nd col.
[10] Rebar, Abstract.

a skilled artisan in view of Rebar would be inspired to instead use toxin molecules as an active agent. Then, the Office opines, a skilled artisan further would modify this twisted interpretation of Rebar by substituting *botulinum* toxin type A for *Clostridium* perfringens.

Although Rebar tangentially discloses *Clostridium* perfringens iota,[12] it is an entirely different species from *botulinum* toxin type A. As the present specification discloses, the "genus *Clostridium* has more than one hundred and twenty seven species" with *Botulinum* toxin being but one of those species.[13] Further, *botulinum* toxin serotype A is one of seven immunologically distinct *botulinum* toxin serotypes. Borodic does not motivate the skilled artisan to substitute a *Botulinum* toxin for *Clostridium* perfringens iota and a skilled artisan would not view these entirely different species of bacteria as substitutable. In addition, Borodic has nothing to do with wound healing. Rather, Borodic applies "botulinum toxin to a number of patients with a variety of neuralgia-related facial pains . . . ."[14] A skilled artisan would not combine Borodic's teaching of a facial pain treatment with *botulinum* toxin type A to modify Rebar's teaching of *Clostridium* perfringens iota as a polypeptide carrier.

Gassner does nothing to remedy the shortcomings of Rebar and Borodic. In fact, independent claims 1, 6, 13, and 15 all require that the patient not have contractures or spasticity. However, Gassner's wounds are those that are "adversely affected by muscle tension or movement.[15] Gassner's teachings are directly opposed to the present claims. Since all claim limitations would not be elucidated by a combination of the cited references, no *prima facie* case of obviousness has been established. In fact, the references direct the skilled artisan away from the treatments of the present claims.

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[11] Rebar, ¶ [0275].
[12] Rebar, ¶ [0275].
[13] Published Specification, ¶ [0017].
[14] Borodic, ¶ [0028], Claims 8 & 12.
[15] Gassner, col. 3, lines 6-8.

CONCLUSION

Applicant respectfully requests that a timely Notice of Allowance be issued in this case. The Commissioner is authorized to charge any fee which may be required in connection with this Amendment, or credit any overpayment, to deposit account No. 50-3207.

Respectfully submitted,

Dated: 2007-12-3

/Joseph Taffy/
Joseph Taffy
Registration No. 50,973
CUSTOMER NUMBER: 45,200

K&L GATES
1900 Main Street, Suite 600
Irvine, California 92614-7319
Telephone: (949) 253-0900
Facsimile: (949) 253-0902